

K122308

## 510(k) Summary of Safety and Effectiveness

OCT 1 2012

### AxSOS™ Locking Plate System

Proprietary Name: AxSOS™ Locking Plate System

Common Name: Bone plates

Classification Name and Reference: Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

Regulatory Class: Class II

Product Codes: 87 HRS: Plate, Fixation, Bone

Predicate Devices: AxSOS™ Locking Plate System

For Information contact: Estela Celi  
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Date Prepared: September 27, 2012

### Description

This Special 510(k) submission is a line extension to address modifications made to the AxSOS™ Locking Plate System which was cleared in K061012. This line extension is to add four femoral long plates to the existing size range of the AxSOS™ Locking Plate System. These monoaxial long plates will be known as AxSOS™ Distal Lateral Femur TS (Threaded Shaft) Long Plates and will be available in two lengths in left and right configurations.

### Intended Use

The AxSOS™ Distal Lateral Femur TS Long Plates line extension does not alter the intended use of the predicate AxSOS™ Locking Plate System as cleared in K061012. The indications for use for the subject plates are provided below.

### Indications

The AxSOS™ Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia and femur.

**Substantial Equivalence:**

The AxSOS™ Distal Lateral Femur TS Long Plates are substantially equivalent to the AxSOS™ Distal Lateral Femur TS Plates of the AxSOS™ Locking Plate System cleared under K061012 in regards to intended use, design, materials, and operational principles as a bone fixation device.

<b>AxSOS™ Locked Plating Comparison of Subject to Predicate</b>		
	<b>Subject Device</b> AxSOS™ Distal Lateral Femur TS Long Plates	<b>Predicate Device</b> AxSOS™ Distal Lateral Femur TS Plates
510(k)	Pending	K061012
Intended Use	Fractures of the Distal Femur	Fractures of the Distal Femur
Design	Monoaxial Plates	Monoaxial Plates
Material	Stainless Steel	Stainless Steel
Plate Sizes	2 lengths/18-20 hole plates	7 lengths/4-16 hole plates

**Summary of Non-Clinical Testing and Evaluation**

Risk analysis was performed according to the requirements of ISO 14971:2007 “Medical Devices-Application of risk management to medical devices.” Records of the risk analysis process are retained in the design history file. Static strength as well as fatigue strength testing has demonstrated the subject plates are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

OCT 1 2012

Howmedica Osteonics Corporation  
% Ms. Estella Celi  
Regulatory Affairs  
325 Corporate Drive  
Mahwah, New Jersey 07430

Re: K122308  
Trade/Device Name: AxSOS™ Distal Lateral Femur TS Long Plates  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: September 11, 2012  
Received: September 12, 2012

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

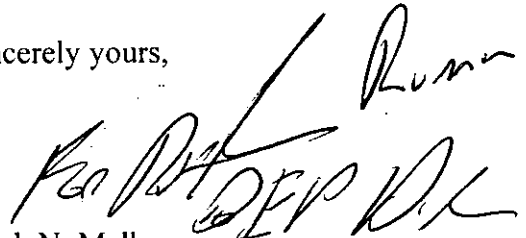
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

APPENDIX E-1

Indication for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: AxSOS™ Distal Lateral Femur TS Long Plates

Indications for Use:

The AxSOS™ Locking Plate System is intended for use in long bone fracture fixation. The system is indicated for fixation of long bone fractures including but not limited to fractures of the humerus, tibia and femur.



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K122308

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)